MEDTECHS LLC

APR 11 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: K080884

Applicant Information:

Date Prepared: March 2, 2008

Name: MTecHS
Division of MedTechs, LLC
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Durham, NC 27703
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Contact Person: Meghan Ath
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Device system Information:

Classification: DPS/Class II/870.2340
Trade Name: QHRV 1 – Health Assessment System
Common Name: HRV Analysis System
Classification Name: Electrocardiograph

Substantial Equivalence:

QHRV-1 is substantially equivalent to the following Predicate Device systems.

Hokanson ANS 2000 RR Interval Measurement	K973426
Q Med Inc., Monitor One NDX HRV Analysis Function	K972991
Ansore Health Management System – Boston Medical	K010955

Intended Use:

QHRV-1 Health Assessment System has the same intended use as the legally marketed predicate device systems. The QHRV -1 System is intended for use in heart variability measurements in response to paced respiration and controlled exercises.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2008

MTechsHS
Division of MedTechs LLC
c/o Ms. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55513

Re: K080884
QHRV 1 – Health Assessment System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 28, 2008
Received: March 31, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510K Number (if known) K080884

Device system Name: **QHRV 1 – Health Assessment System**

Indications for Use: The QHRV 1 – Health Assessment System is intended for (HRV) Heart Rate Variability Measurements in response to a series of paced respiration, standardized and controlled exercises. These measurements and analysis are not intended as clinical diagnosis but only to substantiate appropriate patient health assessment procedures.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080884